

Rx News Bulletin

Bureau of Narcotics & Dangerous Drugs

Missouri Department of Health and Senior Services

health.mo.gov/safety/bnodd/index.php

Required Record Keeping and Accountability

Controlled substance record keeping laws document each movement and activity with controlled substances. A paper trail is established to track each dose from the day it is manufactured, to its shipments through distributors, to the practitioners and eventually to the patients.

Similar to tracking and balancing your checkbook or bank account, all registrants are required to maintain records of all controlled substances they receive and what dates they received them.

Registrants must document each administration, dispensing or other activity to account for all doses entering their practice. Controlled substances must be inventoried annually. Registrants should always have documentation present so that they may perform an audit to determine if any drugs are missing.

All controlled substance activities must be documented in patients' charts. This is not only a requirement of the Missouri Bureau of Narcotics and Dangerous Drugs but is also the requirement of most practice acts from the state licensing boards. The establishment of a patient chart with all components documented is part of the requirement for establishing a legitimate practitioner/patient relationship.



Inside

Packaging and Labeling Requirements for Dispensing	2	Performing an Annual Inventory	3
Proper Documents of Drug Receipt Records	2	Drug Take Back	3

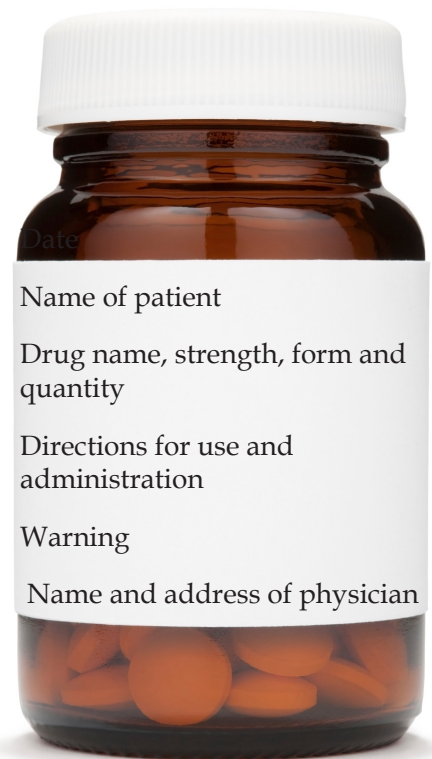
Packaging and Labeling Requirements for Dispensing

When controlled substances are dispensed by individual practitioners, the medications must be dispensed in child-proof packaging. The requirement to use a child-proof lid is found in State Regulation 19 CSR 30-1.066(B) where it states that packing shall comply with the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471 – 1476. The exception to this packaging is if the individual practitioner is dispensing sample medications that are already packaged in FDA approved sample packaging. In this situation, the sample packaging will suffice and there is no need for an additional container.

When controlled substances are dispensed by individual practitioners, they are required to affix a label to the exterior of the drug container. There are no exceptions to this labeling requirement. All containers must be labeled, including factory-packaged samples.

Practitioners must affix their own dispensing label that documents the following:

- ✓ date
- ✓ name and address of the individual practitioner;
- ✓ name of the patient;
- ✓ drug name, strength, form and quantity;
- ✓ directions for use and administration; and
- ✓ a warning that the drugs are for the patient only and it is unlawful to transfer the drugs to any other person. This warning may be part of your label or it may be a separate sticker.



Proper Documentation of Drug Receipt Records

Registrants are required to maintain documentation of all controlled substances that come into their possession. The following documentation is required for controlled substances received:

1. name, address and DEA number of the supplier;
2. name, address and DEA number of the receiver;
3. drug name, strength, form and quantity received; and
4. the date the drugs were received.

A registrant may use a packing slip or invoice to assist them in tracking this information. However the registrant is responsible to review the information and make sure that all of the required information is documented.

Performing an Annual Inventory

All registrants must inventory their controlled substances on hand, at least every 12 months. The BNDD provides a form that registrants may use. The form is on the website on the BNDD website at <http://health.mo.gov/safety/bndd/index.php> under the link to forms. The following documentation must be completed.

1. The inventory must be documented on paper and cannot be electronic. If it were documented electronically, then it must be printed out and dated. A paper copy must be maintained on file for inspection.
2. Schedule II drugs should be inventoried and documented on their own, separately from Schedule III, IV and V drugs.
3. Document the date the inventory was performed.
4. Document the drug names, strengths, forms and quantities on hand.
5. Document whether this inventory was taken before the opening of business, or after the closing of business. If you are open 24 hours-a-day, you document the time the inventory was taken.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
BUREAU OF NARCOTICS AND DANGEROUS DRUGS
ANNUAL INVENTORY OF CONTROLLED SUBSTANCES

REGISTRANT NAME: _____ DATE OF ANNUAL INVENTORY: _____

SCHEDULE(S) INVENTORIED

☐ INVENTORY OF SCHEDULE II DRUGS ONLY (INDIVIDUALLY HAND COUNTED)
☐ INVENTORY OF SCHEDULES III-V DRUGS ONLY
(INVENTORY FOR SCHEDULE II DRUGS MUST BE ON SEPARATE FORM FROM III-V)

TIME OF INVENTORY

☐ INVENTORY TAKEN AT OPENING OF BUSINESS
☐ INVENTORY TAKEN AT CLOSING OF BUSINESS-AFTER HOURS
TIME OF DAY INVENTORY TAKEN, IF OPERATIONS ARE 24 HOURS A DAY: _____

DRUG NAME	DRUG STRENGTH	DOSAGE FORM	QUANTITY



The next national drug take-back day is scheduled for April 27, 2013. Local law enforcement agencies wanting to participate in Missouri may call and receive a packet from the St. Louis DEA Office. Please call (314) 538-4600 and ask to speak to Scott about registering to host a drug take-back location.

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Alternate forms of this publication for persons with disabilities may be obtained by contacting the Missouri Department of Health and Senior Services, BNDD, P.O. Box 570, Jefferson City, MO, 65102, (573) 751-6321. Hearing- and speech-impaired citizens can dial 711. EEO/AAP services provided on a nondiscriminatory basis.